K061730

AUG - 4 2006

# 510(k) Summary

(1) **Submitter's name, address**

Osmetech Inc.
235 Hembree Park Drive
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**Contact Person**

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**Date of preparation of this summary:** June 15, 2006

(2) **Device trade or proprietary name:**

Osmetech OPTI R Critical Care Analyzer

**Device common or usual name or classification name:**

pH, Blood Gas, Electrolyte, hemoglobin and oxygen saturation analyzer

**CLASSIFICATION**

| Product Nomenclature | Regulation | Classification Number | Class | Panel |
|---|---|---|---|---|
| ELECTRODE, ION SPECIFIC, POTASSIUM | 862.1600 | 75 CEM | II | CHEMISTRY |
| ELECTRODE, ION SPECIFIC, IONIZED CALCIUM | 862.1145 | 75 JFP | II | CHEMISTRY |
| ELECTRODE, ION SPECIFIC, SODIUM | 862.1665 | 75 JGS | II | CHEMISTRY |
| ELECTRODE, BLOOD GASES ($PCO_2$,$PO_2$) AND pH | 862.1120 | 75 CHL | II | CHEMISTRY |
| SYSTEM, HEMOGLOBIN, AUTOMATED | 864.5620 | 81 GKR | II | HEMATOLOGY |
| OXIMETER, WHOLE BLOOD | 864.7500 | 81 GLY | II | HEMATOLOGY |
| MULTI ANALYTE CONTROL SOLUTION | 862.1660 | 75 JJY | I | CHEMISTRY |

(3) **Predicate Device Information**

The predicate device is the OPTI R Critical Care Analyzer (formerly AVL OPTI R Analyzer), 510(k) Number K000103, concurrence date.

(4) **Substantial Equivalence**

The OPTI R Analyzer is a modified design of our existing Osmetech OPTI R Analyzer (formerly AVL OPTI R Analyzer) [K000103].

The modified OPTI R Analyzer has the following similarities to those which previously received 510 (k) concurrences:

- have the same indicated use,
- use the same operating principle,
- incorporate the same basic design,
- incorporate the same materials,
- are packaged using the same materials and processes.

In summary, the OPTI R Analyzer described in this submission is substantially equivalent in function, safety and efficacy to the currently marketed predicate device [K000103]. A comparison of features between the modified OPTI R analyzer and the original OPTI R is provided under the tab, **Comparison to Predicate Device.**

**(5) Description of the new device**

The OPTI R Critical Care Analyzer is a small [4.9 x 14.3 x 9.8 in., 10 lbs], microprocessor-based instrument using optical fluorescence for the measurement of pH, $pCO_2$, $PO_2$, sodium, potassium and ionized calcium in samples of whole blood, plasma or serum. In addition, it uses optical reflectance for the measurement of total hemoglobin and oxygen saturation. A multiple use cassette provides up to 50 patient and 42 aqueous quality control samples on a single cassette during a seven day period. The sample count and time is maintained by the analyzer and reported to the user with each sample operation. The cassette contains six optical fluorescence sensors and is packaged in a sealed foil pouch which bears a bar-coded label with calibration and identification information. One of these sensors, the oxygen sensor, is also used for the simultaneous measurements of ctHb and $SO_2$. This bar code is read by 'swiping' the foil pouch through a bar code reader conveniently located on the right side of the OPTI R instrument. This bar coded information is used for a calibration verification of the cassette prior to sample introduction. The cassette is then removed from the pouch and placed into the measuring chamber of the OPTI R and a light-tight cover is closed and secured. The OPTI R performs a calibration as needed, but minimally every 30 minutes or within 30 minutes of every patient's sample utilizing liquid buffer and precision calibration gas, both of which are maintained within the analyzer. The buffer is contained in the OPTI R Fluid Pack and the precision gas is contained in a cylinder. Various checks of mechanical and calibration integrity are performed during this calibration to ensure correct operation and measurement.

The OPTI R aspirates the specimen into the cassette either from a capillary tube, syringe or Osmetech ComfortSampler™, and into position over the fluorescence sensors for pH, $PCO_2$, $PO_2$, $Na^+$, $K^+$, and $iCa^{++}$ as well as ctHb and $SO_2$. During this process, additional checks are made for position and integrity of the sample, measurement stability, and end-point. After the results are displayed and printed

the sample is moved to the waste pouch contained within the OPTI R Fluid Pack. The cassette is then rinsed and calibrated, after which the cassette is ready for the next sample.

Communication to the device is accomplished simply with the use of a touch screen graphical user interface. The analyzer communicates to the user through a color display and with a thermal printer using heat sensitive paper to output measured values, calibration reports, and other information. The data from the analyzer may be communicated to hospital HIS/LIS data systems through an RS232 output terminal.

**(6) Intended use of the device**

The Osmetech OPTI R Critical Care Analyzer is intended to be used for the measurement of pH, $PCO_2$, $PO_2$, sodium, potassium, ionized calcium, total hemoglobin content and oxygen saturation in sample of whole blood, serum or plasma in either a traditional blood gas, clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results.

This is the **same intended use** as previously cleared for the AVL OPTI R, 510(k) Number K000103, with exception of the name change from AVL to Osmetech.

**(7) Conclusions drawn from Verification and Validation Testing**

Analysis of the data collected during verification and validation testing including linearity and precision testing for this device demonstrates that the Osmetech OPTI R Critical Care Analyzer is safe, effective, and equivalent to predicate device [K000103] to which it is compared. The key design verification tests that were performed as a result of the risk analysis are listed under the tab, **Verification and Validation.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Bernie Heitz
VP, Engineering
Osmetech CCD
235 Hembree Park Drive
Roswell, GA 30076

AUG - 4 2006

Re: k061730
Trade/Device Name: Osmetech OPTI R Critical Care Analyzer
Regulation Number: 21 CFR§862.1120
Regulation Name: Blood gases (Pco2, Po2) and blood pH test system
Regulatory Class: Class II
Product Code: CEM, JFP, JGS, CHL, GKR, GLY, JJY
Dated: July 13, 2006
Received: July 25, 2006

Dear Mr. Heitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K061730

***Device Name:*** Osmetech OPTI R Critical Care Analyzer

## *Indications for Use*

**pH**

The pH value of the blood, serum or plasma may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

a) primary bicarbonate deficit - metabolic acidosis
b) primary bicarbonate excess - metabolic alkalosis
c) primary hypoventilation - respiratory acidosis
d) primary hyperventilation - respiratory alkalosis

An increase in blood, serum or plasma pH (alkalemia) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of $CO_2$, due to hyperventilation.

A decreased pH value (acidemia) in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of $H^+$ ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute; as the result of pulmonary edema, airway obstruction or medication, or may be chronic; as the result of obstructive or restrictive respiratory diseases.

Prescription Use ___X__ (Per 21 CFR 801.subpart D) OR Over-The-Counter Use _____ (Per 21 CFR 801.subpart C)

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***$PCO_2$***

The $PCO_2$ value of arterial blood is used to assess how well the body eliminates carbon dioxide, a byproduct of metabolism. A $PCO_2$ value below the normal range is termed respiratory alkalosis and indicates *hypocapnia*, a condition caused by increased alveolar ventilation such as hyperventilation.

An arterial $PCO_2$ above the normal range is termed respiratory acidosis and indicates *hypercapnia*, a sign of ventilatory hypoventilation and failure, resulting from cardiac arrest, chronic obstructive lung disease, drug overdose, or chronic metabolic acid-base disturbances.

***$PO_2$***

The $PO_2$ value of arterial blood is used to assess how well the body is able to absorb oxygen in the lungs. Values below the normal arterial $PO_2$ (*arterial hypoxemia*) are usually caused by pulmonary, circulatory, or respiratory abnormalities (e.g. bronchial obstruction, vascular problems, decrease in cardiac output, increased oxygen demand, anatomical heart defect, low inspired $O_2$ content). Generally, $O_2$ levels above 100 mmHg do not contribute significantly to the oxygen content since, with normal hemoglobin concentrations, 80 - 100 mmHg, $PO_2$ provides a 97% saturation level, and a level greater than 100% cannot be achieved.

***Sodium***

Sodium is the major cation of extracellular fluid. Its primary functions in the body are to chemically maintain osmotic pressure and acid-base balance and to transmit nerve impulses. Sodium functions at the cell membrane level by creating an electrical potential between different cell membranes causing the transmission of nerve impulses and neuromuscular excitability to be maintained. Sodium is involved in some enzyme catalyzed reactions as a cofactor. The body has a strong tendency to maintain a total base content, and only slight changes are found even under pathologic conditions.

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(Per 21 CFR 801.subpart D) (Per 21 CFR 801.subpart C)

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Low sodium values, *hyponatremia*, usually reflect a relative excess of body water rather than a low total body sodium. Reduced sodium levels may be associated with: low sodium intake; sodium losses due to vomiting or diarrhea with adequate water and inadequate salt replacement, diuretics abuse, or salt-losing nephropathy; osmotic diuresis, metabolic acidosis; adrenocortical insufficiency; congenital adrenal hyperplasia; dilution type due to edema, cardiac failure, hepatic failure; and hypothyroidism.

Elevated sodium values, *hypernatremia*, are associated with conditions with water loss in excess of salt loss through profuse sweating, prolonged hyperpnea, severe vomiting or diarrhea, diabetes insipidus or diabetic acidosis; increased renal sodium conservation in hyperaldosteronism, Cushing's syndrome; inadequate water intake because of coma or hypothalamic diseases; dehydration; or excessive saline therapy.

The sodium value obtained may be used in the diagnosis or monitoring of all disturbances of the water balance, infusion therapies, vomiting, diarrhea, burns, heart and kidney insufficiencies, central or renal diabetes insipidus, endocrine disturbances and primary or secondary cortex insufficiency of the adrenal gland or other diseases involving electrolyte imbalance.

***Potassium***

Potassium is the major cation in the intracellular fluid and functions as the primary buffer within the cell itself. Ninety percent of potassium is concentrated within the cell, and damaged cells release potassium into the blood. Potassium plays an important role in nerve conduction, muscle function, and helps maintain acid-base balance and osmotic pressure.

Elevated potassium levels, *hyperkalemia*, can be found in oligouria, anemia, urinary obstruction, renal failure due to nephritis or shock, metabolic or respiratory acidosis, renal tubular acidosis with the $K^+/H^+$ exchange and hemolysis of the blood. Low potassium levels, *hypokalemia*, can be found in excessive loss of potassium through diarrhea or vomiting, inadequate intake of potassium, malabsorption, severe burns and increased secretion of aldosterone. High or low potassium levels may cause changes in muscle irritability, respiration and myocardial function.

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The potassium value obtained may be used to monitor electrolyte imbalance in the diagnosis and treatment of infusion therapies, shock, heart or circulatory insufficiency, acid-base imbalance, therapy with diuretics, all kinds of kidney problems, diarrhea, hyper- and hypo-function of adrenal cortex and other diseases involving electrolyte imbalance.

***Ionized Calcium***

Calcium in blood is distributed as free calcium ions (50%); bound to protein, mostly albumin (40%); and 10% bound to anions such as bicarbonate, citrate, phosphate and lactate. However, only ionized calcium can be used by the body in such vital processes as muscular contraction, cardiac function, transmission of nerve impulses and blood clotting. The OPTI R measures the ionized portion of the total calcium. In certain disorders such as pancreatitis and hyperparathyroidism, ionized calcium is a better indicator for diagnosis than total calcium.

Elevated calcium, *hypercalcemia*, may be present in various types of malignancy, and calcium measurements may serve as biochemical markers. In general, while ionized calcium may be slightly more sensitive, either ionized or total calcium measurements have about equal utility in the detection of occult malignancy. Hypercalcemia occurs commonly in critically ill patients with abnormalities in acid-base regulation and losses of protein and albumin, which gives a clear advantage to monitoring calcium status by ionized calcium measurements.

Patients with renal disease caused by glomerular failure often have altered concentrations of calcium, phosphate, albumin, magnesium and pH. Since these conditions tend to change ionized calcium independently of total calcium, ionized calcium is the preferred method of accurately monitoring calcium status in renal disease.

Ionized calcium is important for diagnosis or monitoring of: hypertension management, parathyroidism, renal diseases, malnutrition, kidney stones, multiple myeloma and diabetes mellitus.

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OR

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510(k) K061730

***total Hemoglobin concentration (ctHb)***

Hemoglobin is the main component of erythrocytes. It serves as the vehicle for transportation of oxygen within the bloodstream and each gram of hemoglobin can carry 1.39 mL of oxygen. The oxygen combining capacity of the blood is directly proportional to the hemoglobin concentration rather than to the number of red blood cells (RBC), because some red cells contain more hemoglobin than others.

Although oxygen transport is the main function of hemoglobin, it also serves as an important buffer in the extracellular fluid. Decreases in the amount of hemoglobin can come about as a result of a decreased concentration of hemoglobin in the erythrocytes, or a decreased number of erythrocytes that contain a normal concentration of hemoglobin.

Decreased levels are found in anemia states, hyperthyroidism, severe hemorrhage and hemolytic reactions due to transfusions of incompatible blood, reaction to chemical, infectious and physical agents as well as various systemic diseases. Increased levels are found in hemoconcentration of the blood, chronic obstructive pulmonary disease and congestive heart failure.

ctHb gives valuable information in an emergency situation if interpreted not in an isolated fashion but in conjunction with other pertinent laboratory data.

ctHb is used to screen for disease associated with anemia, to determine the severity of anemia, to follow the response to treatment for anemia and to evaluate polycythemia.

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***Hemoglobin Oxygen Saturation ($SO_2$%)***

When each heme group of the hemoglobin molecule is associated with one molecule of oxygen, the hemoglobin is referred to as oxyhemoglobin ($O_2Hb$). The amount of oxyhemoglobin, expressed as a fraction of the total functional hemoglobin (able to bind oxygen), is termed hemoglobin oxygen saturation ($SO_2$%). The largest portion (about 98%) of blood oxygen content is the oxygen bound to hemoglobin. The reference interval for arterial blood from healthy adults is typically 94 to 98%.

Decrease in $SO_2$ below the critical level necessary for tissue oxygen saturation is a grave clinical situation. Low oxygen saturation may be caused by many of the same factors responsible for arterial *hypoxemia*. Low fractional oxyhemoglobin ($FO_2Hb$), defined as a fraction of total available hemoglobin, may also be caused by unusually large amounts of non-functional hemoglobins, high concentrations of deoxyhemoglobin, chemically altered hemoglobin or factors affecting the affinity of hemoglobin for oxygen, including: temperature, pH, $PCO_2$, 2,3-DPG concentration and type of hemoglobin.

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For *In Vitro* Diagnostic Use

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